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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/500,586 | 09/09/2004 | Bum-Joon Kim | 038779/28077 | 7698 |
| <div>826 7590 07/27/2007</div> <div>ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000</div> | | | | |
| | | | EXAMINER SWARTZ, RODNEY P | |
| | | | ART UNIT 1645 | PAPER NUMBER |
| | | | MAIL DATE 07/27/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,586

Applicant(s)

KIM ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18April2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Office Action, received 18 April 2007, is acknowledged. Claims 1, 2, 3, 4, 5, 10, and 16 have been amended. Claims 6 and 7 have been canceled.
2. Claims 1-5 and 8-16 are pending and under consideration.

Rejections/Objections Withdrawn/Moot

3. The objection to claim 10 is withdrawn in light of the amendment of the claim.
4. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claim.
5. The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claim.
6. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claim.
7. The objection to Figure 1 is withdrawn.
8. The rejection of claims 1 and 8-15 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.
9. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.
10. The rejection of claims 3 and 4 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.
11. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.
12. The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-5 and 8-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to polynucleotides and primers which are deemed to specifically amplify gene fragments of mycobacterial species. It is unclear how one "specifically" amplify gene fragments of mycobacterial species when the claimed sequences: 1) share identity with other bacteria, i.e., Bifidobacterium, and 2) are sequences "comprising" the listed SEQ ID NOs. The use of the open language, comprising, allows unknown regions of any length on either end of the listed SEQ ID NOs. These unknown regions may also function as primers for unknown nucleic acid sequences. Therefore, because the SEQ ID NOs are not restricted to only mycobacteria and the claimed sequences may include any amount of unknown regions which may function as primers, it is unclear how the claimed specificity is achieved.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

July 17, 2007